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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,320	07/18/2001	Avi Ashkenazi	10466/117	9471

9157 7590 06/17/2003

GENENTECH, INC.
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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Offic Action Summary	Application No.	Applicant(s)	
	09/909,320	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-46,49-52 and 54-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-46, 49-52, 54-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Detailed Office Action

1. Receipt of Applicants' arguments and amendments filed in Paper No.13 on 01 April 2003 is acknowledged. Claims 47-48 and 53 have been canceled and claims 39-44 and 52 have been amended. Thus claims 39-46, 49-52 and 54-58 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No.13, 02/07/03:

(I) The objection to the specification for containing an embedded hyperlink.

(II) The rejection of claims 39-44, 51, 52 made under 35 U.S.C. 112, first paragraph, for lacking complete deposit information for the cDNA with the ATCC accession number 209481.

(III) The rejection of claims 39-58 made under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The declaration under 37 C.F.R §1.132, by Dr. Goddard, filed in Paper No.12, 07 February 2003, for related Application Number 09/903,925 was considered for the current Application and is sufficient to overcome the rejection of claims 39-46, 49-52 and 54-58 based upon 35 U.S.C 101/112.

(IV) The rejection of claims 52-54 made under 35 U.S.C. § 112, second paragraph.

(V) The rejection of claims 39, 52-58 made under 35 U.S.C § 102(b) as being anticipated by Fuso Pharmaceuticals Ind. Ltd (WO 200031277).

(VI) The rejection of claims 39-41, 52-54 made under 35 U.S.C § 102(a) as being anticipated by Yamaguchi et al (May 2001).

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

4. Applicants contend that the claimed subject matter was disclosed in the international PCT application PCT/US99/30095, filed 16 December 1999 (WO 00/37640), therefore, the present application is entitled to the filing date of 16 December 1999.

This argument is found persuasive in part. Only the isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:262 (full length) is afforded the filing date of the parent Application PCT/US99/30095, filed on 16 December 1999. However, the isolated nucleic acid encoding the polypeptide of SEQ ID NO:263, or encoding variants of SEQ ID NO:263, is not supported by the disclosure in the international application PCT/US99/30095, filed 16 December 1999, since this prior application does not provide a specific and substantial asserted utility or a well established utility for the claimed invention.

Accordingly, the subject matter defined in claims 39-46, 49-52 and 54-58 is afforded an effective filing date of 12/16/99 so far as they pertain to the isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:262

Claim Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 39-46, 49-52 and 54-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:262, an isolated nucleic acid comprising a nucleotide sequence which completely hybridizes to the nucleotide sequence set forth in SEQ ID NO:262, does not reasonably provide enablement for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:263 or which encodes variants of SEQ ID NO:263. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claims 39-46, 49-52 and 54-58 are drawn to nucleic acid encoding a polypeptide having 80%, 85%, 90%, 95% and 99% to the polypeptide of SEQ ID NO:262; however, instant specification does not teach how to make or use said nucleic acid. Instant specification discloses a gene amplification assay in Example 92, which demonstrates that PRO343 DNA was 2-9 folds higher in primary lung tumors and in primary colon tumors compared to DNA isolated from normal controls. Therefore, only SEQ ID NO:262 (full length) can be used for diagnostic purposes, because Applicants have not shown that any other nucleic acid or variant, even degenerate variants encoding the same protein was higher in tumor samples as compared to normal samples. Thus, while the nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:262, (full length) may be used to detect cancer cells due to increased copy number, the increased copy number of SEQ ID NO:262 does not provide a readily apparent use for all nucleic acids comprising the nucleotide sequences encoding the

polypeptide of SEQ ID NO:263, or those that encode variants of SEQ ID NO:262, because there is no information regarding whether degenerate variants encoding the same protein, were increased in cancer tumors compared to normal controls.

Furthermore, it is not clear from the specification what types of mutations are allowed in the single, full length probe (i.e SEQ ID NO:262) used in the diagnostic assay without loss of probe specificity, therefore, instant specification does not teach how to use an isolated nucleic acid comprising a nucleotide sequence, which hybridizes less than the full length of SEQ ID NO:262.

The data in the instant specification shows that gene copy number is increased in certain tumor tissue samples, however, it does not necessarily follow that an increase in gene copy number results in increased gene expression and increased protein expression, such that "all possible" nucleic acids encoding the polypeptide of SEQ ID NO:263, or those that encode variants of the polypeptide of SEQ ID NO:263, would be useful diagnostically or as target for cancer drug development. For example, Pennica et al, (1998, PNAS USA 95:14717-14722) discloses that, "An analysis of WISP-1 gene amplification in human colon tumors showed a correlation between DNA amplification and over expression, whereas, over expression of WISP-3 RNA was seen in the absence of DNA amplification. In contract, WISP-2 DNA was amplified in the colon tumors, but mRNA expression was significantly reduced in the majority of tumors compared with the expression in normal colonic mucosa from the same patient", see page 14722, second paragraph of column 1; pages 14720-14721. Therefore, the protein levels cannot be accurately predicted from the level of the corresponding gene.

Thus, while instant specification is enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:262, the specification is non enabling for an isolated nucleic acid encoding the polypeptide of SEQ ID NO:263 or an isolated nucleic acid encoding variants of the polypeptide of SEQ ID NO:263.

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
June 16, 2003

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600